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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,242	09/29/2003	David Utley	9222.16565-CIP DIV	1884
26308	7590	05/03/2005	EXAMINER	
RYAN KROMHOLZ & MANION, S.C. POST OFFICE BOX 26618 MILWAUKEE, WI 53226			VRETTAKOS, PETER J	
		ART UNIT		PAPER NUMBER
		3739		

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/674,242	UTLEY ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Peter J Vrettakos	3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 9-29-03.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-7 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-7 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
     Paper No(s)/Mail Date 3-28-05.
- 4) Interview Summary (PTO-413)  
     Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_.

## DETAILED ACTION

This application is a divisional of 09/556,169 now USPN 6,645,201.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (6,419,673) in view of Farley et al. (6,014,589).

Claim 1. Edwards et al. in view of Farley et al. make obvious a method for forming a pattern of lesions in a tissue region at or near a sphincter in the anal canal (Edwards see figure 1) comprising the steps of providing a support structure (Edwards 100,110) sized and configured for advancement into the anal canal and carrying an array of electrodes (Edwards 113, see figure 3) that are coupled to a source of energy (Edwards patented claim 28) capable of heating tissue when transmitted by the electrodes, including a mechanism (Edwards 132) to selectively retract the electrodes within the support structure and to selectively advance the electrodes in a path outside the support structure to penetrate a tissue region and form, when the energy is transmitted, a pattern of lesions,

inserting the support structure into the anal cavity with the electrodes retracted within the support structure, visualizing (Edwards 118) the dentate line (Farley discloses in col. 14:25-30) and the alignment of the electrodes with respect to the dentate line (Farley discloses in col. 14:25-30) through the support structure, aligning the electrodes in a desired location with respect to the dentate line (Farley discloses in col. 14:25-30), advancing the electrodes to penetrate tissue (Edwards figure 3) at or near a sphincter, and applying energy through the electrodes to create a pattern of lesions in the sphincter.

Claim 2. Edwards et al. in view of Farley et al. make obvious a method for forming a composite lesion in a tissue region at or near a sphincter in the anal canal (Edwards see figure 1) comprising the steps of providing a support structure sized and configured for advancement into the anal canal and carrying an array of electrodes (Edwards 113) that are coupled to a source of energy (Edwards patented claim 28) capable of heating tissue when transmitted by the electrodes, including a mechanism to selectively retract the electrodes within the support structure and to selectively advance the electrodes in a path outside the support structure to penetrate a tissue region and form, when the energy is transmitted, a pattern of lesions, inserting the support structure into the anal cavity with the electrodes retracted within the support structure, visualizing the dentate line (Farley discloses in col. 14:25-30) and the alignment of the electrodes with respect to the dentate line (Farley discloses in col. 14:25-30) through the support structure, aligning the electrodes in a desired location with respect to the dentate line (Farley

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discloses in col. 14:25-30), advancing the electrodes to penetrate tissue at or near a sphincter, applying energy through the electrodes to create a first pattern of lesions in the sphincter, retracting the electrodes, and rotationally (**it would be determined through routine experimentation to rotate the support structure in the tissue region in order to precipitate a composite lesion**) shifting the position the support structure in the tissue region, so that advancement the electrodes a second time forms, when the energy is transmitted, a second pattern of lesions rotationally shifted from the first pattern of lesions, together comprising the composite lesion.

3. A method as in claim 1 or 2 wherein the visualizing of the dentate line is through a sidewall (Edwards (118)) in the support structure. In regards to the shape and placement of the slot / transparent region, the examiner contends that these are device characteristics that could be determined through routine experimentation.

4. A method as in claim 2 wherein the electrodes are deployed through the sidewall (Edwards figure 3).

5. A method as in claim 1 or 2 wherein the energy applied is radiofrequency energy (Edwards col. 9:20-25).

6. A method as in claim 1 or 2 wherein the electrodes are aligned to penetrate internal sphincter muscle (Edwards figure 3).

7. A method as in claim 1 or 2 wherein the electrodes are aligned to penetrate external sphincter muscle (Edwards figure 3).

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Edwards in view of Farley by including a means along the support structure to visualize tissue from within the support structure in order to locate the dentate line (defined in the application as being around 2cm above the anal orifice 16, also element 30). The motivation would be to provide a means for viewing and control of the operation of the support structure as posited in Edwards col. 4:28-31, as well as to minimize pain as disclosed in Farley col. 14:28.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Edwards (6,149,673).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

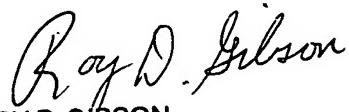
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pete Vrettakos  
April 28, 2005



  
ROY D. GIBSON  
PRIMARY EXAMINER